

**TITLE: Managing Conflicts of Interest****1.0 PURPOSE**

This Standard Operating Procedure (SOP) sets forth the policies and procedures for the VA Central IRB, its support staff, investigators, and local participating facilities in a research project overseen by the VA Central IRB to identify, evaluate, and manage any perceived or actual conflicts of interest involving the research projects brought before the VA Central IRB for review. These conflicts can be financial or another type of conflict such as personal or business relationships.

**2.0 REVISION HISTORY**

Date of Initial Approval	July 1 2008
Revision Dates	November 3, 2008 December 19, 2008 April 17, 20009 September 3, 2009 March 17, 2010

**3.0 SCOPE**

3.1 This SOP applies to all research projects involving human participants submitted to the VA Central IRB for review. The impact of conflicts may occur in any phase of the project, from the development of the project design to management and oversight of an approved project. Conflicts may also bias project reviews, analysis of data, and dissemination of the project results through publications and presentations.

3.2 All VA investigators, whether compensated or uncompensated, whether part-time or full-time, must comply with all VA and other requirements relating to conflict of interest. For each project submitted for review, the Principal Investigator/Study Chair (PI/SC), Co-PI/SC, investigators, and collaborators contributing five percent or more effort are required to disclose any perceived or actual conflicts of interest.

3.3 Additionally, all VA Central IRB members, whether voting or nonvoting, are required to disclose any perceived or actual conflict of interest according to the requirements in this SOP.

3.4 This SOP also addresses perceived or actual institutional conflict of interest within the Veterans Health Administration Central Office and the Office of Research and Development (ORD) as the organizational entities in which the VA Central IRB operates and functions, and from which it receives its budgetary support.

## **4.0 POLICY**

4.1 It is the policy of the VA Central IRB that any conflicts of interest by investigators are appropriately disclosed and managed or resolved so they do not negatively impact human research participants.

4.2 It is the policy of the VA Central IRB that any VA Central IRB member having a conflict of interest with any projects being reviewed by the IRB recuse themselves so as to not negatively impact the impartiality of the VA Central IRB research project review processes. It is also the policy of the VA Central IRB, in accordance with federal personnel policy, that no VA Central IRB member may accept a gift from a prohibited source or a gift that is given based on the members' position on the IRB.

4.3 It is the policy of the VHA Human Research Protection Program (HRPP) that the VA Central IRB operates independently and free from any organizational conflicts.

4.4 All VA personnel are expected and obligated to follow the Ethical Conduct for Employees of the Executive Branch.

## **5.0 DEFINITIONS**

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

## **6.0 RESPONSIBILITIES**

6.1 All investigators or project team members spending more than five percent of their work time on a particular research project are responsible for the disclosure of any perceived or actual financial conflicts of interest that they or their immediate family members may have related to the proposed project. Disclosure includes any compensation that may be affected by the outcome of the project. In addition, investigators must comply with COI management plans as directed by their local VA facilities and the VA Central IRB. Investigators are also responsible for identifying any perceived COIs that may develop during the course of the project.

6.2 Local VA facilities are responsible for reviewing the financial disclosure forms submitted by their investigators who are planning to participate in a project that is being submitted to the VA Central IRB for review. The local VA facilities are responsible for carrying out the following functions in accordance with their local SOPs:

- Determining whether there are actual or perceived FCOI that could affect an investigator's proposed, current, or future research activities
- Determining whether conditions or restrictions, if any, need to be imposed to manage, reduce, or eliminate the conflicts
- Reviewing any updates to the financial disclosure forms submitted by investigators and making a determination regarding the need to modify requirements for management of the FCOI
- Reviewing individual projects or summaries of projects and the investigator's plan to manage any FCOI if applicable

- Reporting findings and identifying steps to manage the FCOI to the VA Central IRB and the investigator
- Establishing a process, in conjunction with the VA Central IRB, that uses specified evaluation criteria to allow the investigator to appeal a decision restricting the conduct of a project and requiring specific steps to manage, reduce or eliminate the FCOI
- Determining, in conjunction with the VA Central IRB, whether compelling circumstances exist that would permit an investigator having a FCOI that cannot be adequately managed, reduced, or eliminated, to conduct the project
- Maintaining records of all financial disclosure forms, and all actions taken by the local VA facility with respect to identified conflict of interest for the time period that the project records are to be maintained per VA requirements

6.3 The VA Central IRB is responsible for reviewing and requiring, if necessary, appropriate changes in research involving human participants if the VA Central IRB determines the research may be affected by actual or perceived financial or other types of conflicts of interest. The VA Central IRB may also make a determination that a certain research project should not be conducted at a specified local VA institution. In making these determinations, the VA Central IRB considers the actions and recommendations of the local VA facilities if applicable.

6.4 VA Central IRB members are responsible for recusing themselves from review of all projects for which they have a conflict of interest. Members will leave the room, or if participating by video or teleconference, they will disconnect from the meeting.

## 7.0 PROCEDURES

7.1 Investigator Financial Conflict of Interest: Investigator FCOI will be identified and managed as follows:

7.1.1 All investigators or other personnel associated with a project to be reviewed by the VA Central IRB who are contributing five percent or more effort, must complete a financial disclosure form and have it reviewed by their local VA facility in accordance with the local VA facility policies and procedures. In the event that the local facility cannot do this review, such as if the FCOI reviews are done by the local affiliate IRB, the investigator completes VA Central IRB Form 135, Investigator Conflict of Interest Attestation and Disclosure (Attachment 1) and signs it after reading the handout "VA Standards of Ethical conduct and What may Constitute a Real or Potential Conflict of Interest (Attachment 2)

7.1.2 The findings of the local VA facility are submitted to the VA Central IRB as part of the Local Site Investigator Application package, or the Principal Investigator/Study Chair New Project Application as applicable. The findings can also be submitted directly to the VA Central IRB by the local VA facility.

7.1.3 Upon receipt of the Local Site Investigator Application package and/or the Principal Investigator/Study Chair New Project Application, VA Central IRB administrative staff members review the package to determine if the findings of the local

VA facility or the VA Central IRB Forms 135 are attached or if they are still pending receipt. If they are not attached, a staff member contacts the local VA facility to obtain them. For Cooperative Program Studies (CSP), a copy of the CSP Program Statement of Disclosure signed by the investigator is acceptable if no FCOI was identified.

7.1.3.1 Upon receipt of the local VA facility FCOI findings or the VA Central IRB Forms 135, the VA Central IRB administrative staff reviews them to see if any FCOI was identified. If no FCOI was identified, the findings are filed in the project folder and a copy included with the study application. If a potential FCOI was identified and ruled out, applicable documentation from the VA facility's Office of Regional Counsel ruling out the FCOI must also be provided and kept on file.

7.1.3.2 If any FCOI is identified, the applicable local facility FCOI Committee, FCOI Officer's findings, or VA Central IRB Forms 135 are included as part of the project package that is reviewed by the convened VA Central IRB. Projects in which a FCOI is identified are not reviewed under the expedited review procedure, even if the project is otherwise qualified for such review.

7.1.3.3 If upon review of the project package any of the assigned reviewers (Primary, Secondary, or Informed Consent) or the Presiding Chair determines that further clarification is needed regarding the findings of a local VA facility, they may request that copies of the local disclosure forms in question be forwarded for review.

7.1.4 If a FCOI was identified, the convened VA Central IRB reviews the project, to include all materials given to potential participants, the Local Site Investigator Application and/or the Principal Investigator/Study Chair New Project Application as applicable, and the findings of the local VA facility or the VA Central IRB Forms 135, to determine the following:

- The nature of the project to include its scientific and scholarly integrity
- The magnitude of the financial conflict of interest
- The degree to which the financial conflict of interest is related to the project
- The extent to which the project could be directly and substantially affected by the financial conflict of interest
- The potential harm to research participants or the potential for coercion or undue influence during the selection or consenting process
- Whether methods used for management of financial interest of parties involved in the project adequately protect the rights and welfare of participants
- Whether other actions are necessary to minimize risks to participants

7.1.5 Based on its review, the VA Central IRB may agree with the actions of the local VA facility or it may decide to place additional conditions or restrictions on the investigator or the project to resolve or manage the FCOI, or in the case of review of the VA Central IRB Forms 135, it may impose a management plan consisting of restrictions and/or conditions. Examples of conditions or restrictions the VA Central IRB might impose on the investigator or project include but are not limited to the following:

- Public disclosure in publications and/or disclosure in consent forms to include the kind, amount, and level of detail of the information to be disclosed regarding the source of funding, funding arrangements, financial interests of parties involved in the project, and any financial interest management techniques applied
- Monitoring of the project by independent reviewers
- Modification of the project plan or of the roles of particular research staff
- Disqualification from participation in all or a portion of the project that would be affected by the FCOI
- Divestiture of conflicted financial interests in a reasonable period not to exceed 90 days from the date the divestiture is directed, except in cases of unusual hardship
- Severance of relationships that create actual or perceived conflicts

7.1.6 The results of the FCOI review determination by the VA Central IRB are communicated in writing to both the investigator and the local facility R&D Committee, with a copy of this communication filed in the project file kept on file in the VA Central IRB Administrative Office. This can be part of the letter to the investigator detailing any other required modifications or it can be a separate communication as determined by the VA Central IRB upon completion of its review. The review and determination of the VA Central IRB is also recorded in the meeting minutes.

7.1.7 When submitting continuing review reports, investigators must indicate on the continuing review request whether there has been any change in their FCOI status or the status of their team members.

7.1.7.1 The VA Central IRB requires that if a new reportable FCOI occurs prior to the due date for the continuing review report, the investigator must report the new FCOI immediately to the local VA facility in accordance with the local VA facility SOPs. An investigator will be considered noncompliant if such a change is not reported in a timely manner.

7.1.7.2 The findings of the local VA facility are then forwarded to the VA Central IRB within 30 days of the findings being rendered. If the new FCOI occurs within 30 days of the continuing review report submission, the findings of the local VA facility may be included as an attachment to the continuing review report.

7.1.8 When a new FCOI is reported, whether during continuing review or prior to continuing review, the VA Central IRB must consider all the issues listed in paragraph 7.1.4.

7.1.8.1 The VA Central IRB can make any of the same decisions as detailed in paragraph 7.1.5. In addition, the VA Central IRB may make the following additional stipulations:

- Re-obtaining consent from participants and/or removing the investigator from a direct role in participant selection or obtaining consent
- Investigator resignation or removal with appropriate substitution
- Modifying the project and/or the consent process or form

- Requiring that conflicts of interest be disclosed in all publications or presentations of the project.

7.1.8.2 The results of the VA Central IRB's review are documented and reported to both the investigator and the local R&D Committee as detailed in paragraph 7.1.6.

7.1.9 Whether during initial review, continuing review, or any other type review, if the VA Central IRB determines that a FCOI exists that compromises the rights and welfare of human participants or the outcome of the project, it may determine that the conflicts can not be sufficiently managed, reduced, or eliminated. The VA Central IRB can, as applicable, disapprove the project, terminate the project approval, or require that those investigators with the conflicts be eliminated as part of the project team.

7.1.10 Investigators who do not appropriately disclose all FCOI pertaining to their projects or who do not adhere to approved management plans may be barred from submitting any further research projects to the VA Central IRB for review. Such failure is treated as investigator non-compliance and the procedures as set forth in VA Central IRB SOP 118, Serious and Continuing Non-compliance, are then followed.

7.2 VA Central IRB Member Conflict of Interest: The same definitions pertaining to what constitutes a conflict of interest as apply to investigators also apply to VA Central IRB members. VA Central IRB member conflicts of interest are identified and managed as follows:

7.2.1 All VA Central IRB members, whether voting or non voting, are required to complete a VA Central IRB Form 102, Conflict of Interest Attestation (IRB Members) per VA Central IRB SOP 102, VA Central IRB Membership Policies, upon initial appointment and upon re-appointment if applicable. Prior to completing this form, they must be given a copy and read the "VA Standards of Ethical Conduct and What May Constitute a Real or Perceived Conflict of Interest" prepared specifically for VA Central IRB members. More information on these documents can be found in VA Central IRB SOP 102.

7.2.2 No VA Central IRB member will participate in the initial or continuing review of any project; the review of any project modifications; or the review of issues, complaints, or noncompliance with regulations or VA IRB policies and procedures, in which they, an immediate family member, or any individual whose financial interests can be imputed to the member, has a perceived or actual financial or personal COI, except to provide information requested by the VA Central IRB.

7.2.2.1 A VA Central IRB Form 127, Conflict of Interest Declaration (Attachment 3), is included in each VA Central IRB member's agenda package that is distributed prior to a convened Board meeting.

7.2.2.1.1 Each member reviews the agenda and completes the form indicating whether or not the member has any conflict of interest with any of

the projects scheduled to be reviewed. This includes new projects, continuing reviews, and any other actions such as reported issues, complaints, or reports of noncompliance.

7.2.2.1.2 VA Central IRB members attending a convened meeting in person bring the VA Central IRB Form 127 to the meeting and turn it in prior to the meeting being convened. If the member is participating in the meeting by video or teleconference, the form is faxed or scanned and e-mailed to the VA Central IRB Administrative Office prior to the start of the meeting.

7.2.2.1.3 Prior to commencing the project review portion of a VA Central IRB meeting, members are reminded by the VA Central IRB Presiding Co-Chair of the COI policies. This reminder is documented in the meeting minutes. Copies of the VA Central IRB forms 127 will be kept on file in the in the VA Central IRB Meeting Administrative files.

7.2.2.1.4 VA Central IRB members having a COI must declare it prior to the review of the project and recuse themselves from the meeting room when the project is reviewed, except when requested by the VA Central IRB Presiding Chair to remain present to provide information. After the member provides any requested information, the member must leave the meeting room until after completion of the project review by the VA Central IRB and the vote is taken and recorded. If members are participating by video or teleconference, they must disconnect and then be re-connected after the VA Central IRB has made its determination and the vote recorded.

7.2.2.1.5 The absence of a member due to a COI on a particular project is annotated in the minutes to include the member's name, the time left, and the time returned. The member having a conflict of interest does not count towards quorum.

7.2.2.2 If a VA Central IRB member is assigned to serve as a reviewer for a project in which the member has a COI, whether the review is at a convened meeting or is being expedited, the member informs the VA Central IRB Administrator. The COI is documented by the VA Central IRB member on the applicable reviewer checklist or worksheet as applicable and returned to the VA Central IRB Administrative Office. The project is then assigned to another member by one of the Co-Chairs. The VA Central IRB Coordinator keeps a copy of the checklist or worksheet in the member's file and prepares a new worksheet and/or checklist for the new reviewer as applicable.

7.2.2.3 If a VA Central IRB member is unsure whether a conflict of interest exists, the member may consult a Deputy Ethics Officer within the VHA Office of General Counsel (OGC) or the OGC or Ethics representatives on the Board.

7.2.2.4 Non-voting members are subject to the same COI policies and procedures as voting members. This includes non-affiliated WOC employee members, other affiliated WOC members, and other VA employee members.

7.2.2.5 Ad hoc consultants must return a project without any recommendations to the VA Central IRB if they have a COI. They indicate the COI on the reviewer checklist and return it, along with the project documentation.

7.2.3 The VA Central IRB Administrator ensures that VA Central IRB members receive continuing education in conflict of interest policy at least annually.

7.2.4 All documentation regarding VA Central IRB member COI is kept on file the member folders or in the VA Central IRB Meeting administrative files as applicable and is accessible if required for auditing and monitoring purposes.

7.2.5 If a VA Central IRB member fails to disclose a COI, the CRADO, or the IO if the member is a Co-Chair, may terminate their membership on the Board. If the individual is a VA employee located at a local VA facility, the ACOS of the VA facility will be informed of the COI and the failure to disclose of it appropriately. If requested by the CRADO or IO, a review of all the research in which the affected member had a vote will be conducted to determine if any further action regarding those projects is required.

7.3 Institutional Conflicts of Interest: Within the VHA HRPP, Institutional COI is managed as follows:

7.3.1 There may be situations in which ORD might have an interest in seeing a project it funds approved against the better judgment of the VA Central IRB or it may want a project to move more quickly through the review process than the VA Central IRB is comfortable moving it. These are some examples of a potential Institutional COI.

7.3.2 To guard against such potential COIs, the VA Central IRB deliberations and decisions are independent of the funding services within ORD. The VA Central IRB had the final authority to approve research. Such independence is established based on the nationally diverse membership of the VA Central IRB, as well as oversight by the Office of Research Oversight (ORO) and the Principal Deputy Under Secretary for Health (PDUSH), who serves as the Institutional Official (IO) for the VHA Central Office Human Research Protections Program (HRPP).

7.3.3 If a project involves a patent, the VA Central IRB is notified by the Technology Transfer Office of the approved patent. Any potential conflict of interest will be evaluated by the VA Central IRB in consultation with the Office of General Counsel prior to approval of the research.

## 8.0 REFERENCES

8.1 5 CFR 2635, Standards of Ethical Conduct for Employees of the Executive Branch

8.2 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects.

8.3 21 CFR 54, Food and Drug Administration, Financial Disclosure by Clinical Investigators



8.4 FDA Guidance, Financial Disclosures by Clinical Investigators, March 20, 2001

8.5 VHA Handbook 1200.01, The Research and Development (R&D) Committee

8.6 VHA Handbook 1200.18, Intellectual Property

8.7 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.

8.8 Chief Research and Development Officer Memorandum dated September 23, 2005, Financial Conflicts of Interest in Research

### 3 Attachments

1. VA Central IRB Form 135, Investigator Conflict of Interest Attestation and Disclosure
2. Investigator Handout on VA Standards of Ethical Conduct and What May Constitute a Real or Potential Conflict of Interest
3. VA Central IRB Form 127, VA Central IRB Member Conflict of Interest Declaration

I have reviewed and approved the content of this SOP.



K. Lynn Cates, MD  
Director, PRIDE

Date: 4/2/2010

# Investigator Conflict of Interest Attestation and Disclosure



## Prior to completing this form, all investigators must read the attached, "VA Standards of Ethical Conduct and What May Constitute a Real or Potential Conflict of Interest"

- This form must be completed, signed and submitted by each principal investigator, co-principal investigator, investigator and collaborator who plans to devote five percent or more effort to the proposed project.
- The completed and signed attestation must be submitted to the VA Central IRB for review and a COI determination. Submission can be by fax, express mail, or digitally signed encrypted or pass-word protected e-mail.
- COI attestations will be reviewed by VA Central IRB administrative staff and all forms in which a real or potential COI is identified will be reviewed at a fully convened meeting of the VA Central IRB.
- All information contained in this form will remain confidential and have only limited distribution.

**NOTE:** If any real or potential conflicts of interest are identified, the conflicts must be resolved or managed per guidance from the VA Central IRB and if required, the assistance of your VA facility's Regional Counsel or, for VA Central Office WOC employees, the Office of the General Counsel within the VA Central Office. Further, even if no conflicts of interest are identified, your financial holdings or arrangements may still pose a conflict of interest within the meaning of Chapter 11 of Title 18, United States Code, and the Executive Branch Standards of Conduct at 5 CFR Part 2635. Compliance with VA conflict of interest policies may not necessarily satisfy the requirements of these criminal and regulatory conflict of interest provisions. If you have questions regarding these requirements, you can contact your local Regional Counsel for assistance. If you are a WOC appointed through the Central Office, you can contact the Assistant General Counsel for Professional Staff Group III (023).

Please complete each of the following sections as applicable. Attach additional continuation sheets if necessary.

### Section 1

#### Background:

1. Full Name:
2. Title of Proposal:
3. Funding Sources/ Sponsors:
4. Estimated Start Date:
5. Projected End Date:
6. Role (check one): ☐ Principal Investigator ☐ Co-Principal Investigator ☐ Co- Investigator  
☐ Investigator ☐ Study Coordinator ☐ Collaborator ☐ Other:
7. You are a: ☐ VA Employee ☐ VA Contract ☐ Without Compensation (WOC) Appointment  
☐ IPA or SGE ☐ Dual VA and University Appointment (Indicate # of 8ths VA: \_\_\_\_\_)  
☐ Other (Please specify status: ) \_\_\_\_\_
8. Percent of Effort on Research Protocol:

## Section 2

### Conflict of Interest Declaration and Disclosure

**Investigators must check one of the below boxes:**

- ☐ I have read the attached "VA Standards of Ethical Conduct and What May Constitute a Real or Potential Conflict of Interest" and attest that I **do not** have a real or potential conflict of interest in regard to the protocol referenced on this attestation, nor do any of my immediate family members, any other imputed interests or anyone with whom I am involved in a covered relationship.
- ☐ I have read the attached "VA Standards of Ethical Conduct and What May Constitute a Real or Perceived Conflict of Interest" and attest that I **do** have a real or what may be perceived to be a conflict of interest in regard to the protocol referenced on this attestation. The specific real or perceived conflict of interest is detailed below:

## Section 3

### Conflict of Interest Attestation

I certify that, to the best of my knowledge and belief, all of the information on this attestation is true, correct, complete, and made in good faith. I understand that false or fraudulent information on this disclosure may be grounds for the VA Central IRB not accepting the research proposal for review and may be punishable by fine or imprisonment (U.S. Code, Title 18, section 1001). Furthermore, if my financial interest and arrangements, or those of my spouse and dependent children, change from the information provided above during the course of the study, or up to one year following completion of this protocol, I will promptly notify the VA Central IRB Administration Office promptly.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

#### Section 4

#### COI Review Determination by VA Central IRB

This Conflict of Interest attestation and associated protocol have been reviewed for compliance with applicable policies and regulations and for a determination of the existence of a financial or other conflict of interest by a member of the VA Central IRB administrative staff.

*One of the following must be checked:*

- ☐ A real or potential conflict of interest was not identified.
- ☐ A real or potential conflict of interest was identified.

If a real or potential conflict of interest has been identified, the attestation will be forwarded to a fully convened meeting of the VA Central IRB for review. If no COI was identified, this form will be filed in the study file.

\_\_\_\_\_  
Signature of VA Central IRB Administrative Staff  
Reviewer

\_\_\_\_\_  
Date

***For VA investigators involved in human subjects research***

**VA Standards of Ethical Conduct and What May  
Constitute a Real or Potential Conflict of Interest**

**Basic Obligations of Public Service**

Public service is a public trust. To ensure that every citizen and human subject can have complete confidence in the integrity of the Department of Veterans Affairs research protocol submission, approval, and monitoring processes, as well as in the conduct of the research, each VA investigator and the associated VA research protocol support staff must respect and adhere to the principle of ethical conduct as set forth in 5 CFR 2635, Standards of Ethical Conduct for Employees of the Executive Branch, and must disclose and manage any conflicts of interest.

The following principles apply to all government employees:

- Public service is a public trust, requiring employees to place loyalty to the Constitution, the laws, and ethical principles above private gain.
- Employees shall not hold financial interests that conflict with the conscientious performance of duty.
- Employees shall not engage in financial transactions using nonpublic government information or allow the improper use of such information to further any private interest
- Employees shall not solicit or accept any gift or other item of monetary value from any person or entity seeking official action from, doing business with, or conducting activities regulated by the employee's agency, or whose interests may be substantially affected by the performance or nonperformance of the employee's duties.
- Employees shall not use public office for private gain.
- Employees shall act impartially and not give preferential treatment to any private organization or individual.
- Employees shall protect and conserve public property and shall not use it for other than authorized activities.
- Employees shall not engage in outside employment activities, including seeking or negotiating for employment, that conflict with official government duties and responsibilities.

While all government employees must adhere to all the above principles, there are several of these principles which investigators involved in human subjects research can expect to receive greater scrutiny. These involve real or potential conflicts of interest, particularly financial, and the acceptance of gifts.

## Financial Conflicts of Interest (FCOI)

In accordance with 5 CFR 2635, government employees are prohibited from participating personally and substantially in an official capacity in any particular matter in which, to his/her knowledge, he/she or any person whose interests are imputed to him/her has a financial interest, if the particular matter will have a direct and predicable effect on that interest. A particular matter will have a direct effect on a financial interest if there is a close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest. An effect may be direct even though it does not occur immediately.

The financial interests of the following persons are considered to be **imputed** interests to the investigator and will serve to create conflicts of interest for an investigator to the same extent as if they were the investigator's own interests:

- Employee's spouse
- Employee's minor child
- Employee's general partner in a business
- An organization in which the employee serves as officer, director, trustee, general partner, or employee
- Any person with whom the employee is negotiating or has an arrangement concerning prospective employment

The following are considered significant financial conflicts of interest including but not limited to the following monetary interests, as qualified by the following paragraphs:

- Non-VA salary or other payments for services from private or for-profit entities (e.g., consulting fees or honoraria)
- Compensation to the investigator if the amount of the compensation could be affected by study outcome
- Equity interests (e.g., stocks stock options, or other ownership interests)
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights) that would reasonably be expected or appear to affect the proposed research
- Consulting fees, honoraria, gifts, or other "in kind" compensation from a financially interested company for any purpose not directly related to the reasonable costs of the research that in the aggregate have in the prior calendar year exceeded \$10,000, or are expected to exceed that amount in the next 12 months
- Any non-royalty payments or entitlements to payments in connection with the proposed research that are not directly related to the reasonable costs of the research, including any bonuses or milestone payments to the investigators in excess of reasonable costs incurred
- Service as an officer, director, or in any other fiduciary role for a company with financial interests in the proposed research

**NOTE:** A FCOI can only be ruled out by consultation with a Deputy Ethics Officer within the VA Office of General Counsel, or within the Office of General Counsel at the VA Central Office.

Significant financial conflicts of interest do **not** include:

- Salary, royalties or other remuneration from the applicant's home institution
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
- Income from service on advisory committees or review panels for public or non-profit entities

### **Acceptance of Gifts**

With a few exceptions, an investigator who is a government employee, shall not, directly or indirectly, solicit or accept a gift from a **prohibited source** or which is given because of the employee's official position or function.

A **prohibited source** is any person who meets one or more of the following criteria:

- Is seeking official action by the employee's agency
- Does business or seeks to do business with the employee's agency
- Conducts activities regulated by the employee's agency
- Has interests that may be substantially affected by performance or nonperformance of the employee's official duties
- Is an organization, the majority of whose members are engaged in or have interests in the activities described in the above bullets

In general, a government employee may not:

- Accept a gift in return for being influenced in the performance of an official act or doing a particular research project
- Solicit or coerce the offering of a gift
- Accept gifts from the same or different sources on a basis so frequent that a reasonable person would be led to believe the employee had a conflict of interest
- Receive any salary or any contribution to or supplementation of salary from any source other than the United States as compensation for services as a government employee
- Accept vendor promotional training contrary to applicable regulations, policies, or guidance relating to the procurement of supplies and services for the government.

A gift is any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, or other item having monetary value. It includes services as well as gifts of training, transportation, local travel, lodgings and meals, whether provided in-kind, by purchase of a ticket, payment in advance, or reimbursement after the expense has been incurred. It **does not** include the following:

- Modest items of food and refreshments, such as soft drinks, coffee, and donuts, offered other than as part of a meal
- Greeting cards and items with little intrinsic value, such as plaques, certificates, and trophies, which are intended solely for presentation
- Loans from banks and other financial institutions on terms generally available to the public
- Opportunities and benefits, including favorable rates and commercial discounts,

available to the public or to a class consisting of all federal government employees, whether or not restricted on the basis of geographic considerations

- Rewards and prizes given to competitors in contests or events, including random drawings, open to the public unless the employee's entry into the contest or event is required as part of their official duties
- Pension and other benefits resulting from continued participation in an employee welfare and benefits plan maintained by a former employer
- Anything which is paid for by the government or secured by the government under government contract
- Anything for which market value is paid for by the employee

There are many exceptions to the prohibition on accepting gifts. Only a few of the more common ones are detailed below. **When in doubt about the acceptance of a gift, you should contact your Regional Counsel.**

- A government employee may accept unsolicited gifts having an aggregate market value of **\$20.00 or less per source per occasion** provided that the aggregate market value of the individual gifts received from any one person shall not exceed **\$50 in a calendar year**. This exception does not apply to gifts of cash or of investment interests such as stock, bonds, or certificates of deposit, which are strictly prohibited.
- A government employee may accept a gift given under circumstances which make it clear that the gift is motivated by a family or personal friendship rather than the position of the employee. Relevant factors in making such a determination include the history of the relationship and whether the family member or friend personally pays for the gift.
- A government employee may accept discounts and other similar opportunities and benefits if they are offered to all government employees or to members of a group, class, or organization to which the government employee belongs that is not related to their government employment or does not otherwise discriminate among government employees on the basis of their official position or rank.

### **Other Potential Conflicts of Interest**

Two other areas that may result in a conflict of interest or the appearance of a conflict of interest that require a short mention are the **use of nonpublic information and compensation for teaching, speaking and writing.**

An investigator shall not engage in a financial transaction using nonpublic information, nor allow the improper use of nonpublic information to further his/her own private interest or that of another, whether through advice or recommendation, or by knowing unauthorized disclosure. Nonpublic information is information that the employee gains by reason of federal employment and that he/she knows or reasonably should know has not been made available to the general public.

Finally, an investigator should not receive compensation from any source for teaching, speaking, and writing other than the government, that relates to his/her official duties. This generally means an employee may not be compensated for teaching, speaking, or writing on any matter to which the employee is presently assigned or to which the employee had been assigned during the previous one-year period or on any ongoing or announced policy, program, or operation of the employee's agency. There are many nuances to this particular prohibition, such as teaching certain courses in a regularly



established curriculum of an institution of higher education. Again, if in doubt, please consult your Regional Counsel.

### **Disclosure of Conflicts of Interest**

Where an investigator knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interests of any of his/her imputed interests or where the investigator determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his/her impartiality in the matter, the investigator must either **divest** or have his imputed interests divest the financial interests in question or **disclose** those interests to the VA Central IRB. Otherwise, the investigator should not participate in the research.

The VA Central IRB will review such disclosures and inform the investigator whether such interests must be divested prior to the investigator's participation in the research or whether the conflict of interest can be managed in accordance with an approved management plan.

The investigator must also report any change in his/her conflict of interest status to the VA Central IRB within 30 days of the conflict occurring and update his/her conflict of interest status upon submission of continuing review reports.

***After reading this information, each investigator listed on a protocol being submitted to the VA Central IRB for review that is contributing five percent or more effort, must complete a VA Central IRB Form 103, Investigator Conflict of Interest Attestation and submit it to the VA Central IRB Administrative Office as part of a new protocol submission or, if applicable as part of a continuing review report submission or at any time during the conduct of an approved protocol upon occurrence of a conflict.***

# Conflict of Interest Declaration (IRB Members)



*This form is to be used by VA Central IRB members to declare any conflict of interest with projects to be reviewed at a convened meeting of the VA Central IRB.*

## Instructions:

1. The Conflict of Interest Declaration below must be signed after you review the VA Central IRB meeting agenda.
2. The Conflict of Interest Declaration must be updated prior to the meeting if any additional projects have been added to the agenda.
3. At the meeting, all VA Central IRB members must turn-in these forms prior to the start of the meeting. Members attending via video or teleconference should fax or scan and e-mail the form to the VA Central IRB Administrative Office prior to the meeting.
4. Members having a conflict of interest with a particular project must declare it prior to the discussion of the project and leave the room during the discussion and voting. Members participating via video or teleconferencing must disconnect. Members will be summoned to return upon completion of the voting. Members participating via teleconference will be called to reconnect.
5. Members may remain in the room or in the call if requested by the Co-Chair to provide information but must leave or disconnect after the information has been presented.

## CONFLICT OF INTEREST DECLARATION

I have reviewed the agenda for the VA Central IRB meetings to be held on **{DATE}**.

*Please check one of the below boxes:*

<input type="checkbox"/>	I have reviewed the agenda for the above meeting and am not involved in and have no other conflict of interest regarding any of the projects to be reviewed at the above meeting. I will promptly update this declaration should I discover such a conflict during the meeting.
<input type="checkbox"/>	I am involved or I have another type of conflict of interest in the projects listed below. I will leave the room during any discussion and vote on these projects. I have no other conflicts of interest regarding any of the other projects to be reviewed. I will promptly update this declaration should I discover such a conflict during the meeting.

*List of projects in which a conflict of interest is being declared:*

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\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Printed Name: \_\_\_\_\_